



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Peter Tung at 240-669-5483 or peter.tung@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows:

Novel Compositions of Matter Comprising Stabilized Coronavirus Antigens and Their Use.

Description of Technology:

Using a computational design methodology, SARS-CoV-2 spike proteins containing engineered amino acid changes to the receptor binding domain (RBD) were designed. These engineered spike proteins improved the immune response upon immunization of animals. An engineered RBD was also expressed at greater yield, had increased temperature stability, and improved the immune response upon immunization of animals. Specifically, the disclosed RBD designs can be produced approximately 7 times more efficiently than the native sequence, facilitating vaccine manufacturing on a global scale. The disclosed designs also have up to 10 °C

higher thermal stability than the native sequence, suggesting enhanced stability during storage and when in the body. Finally, immunization of animals with the disclosed antigens produces up to 10-fold higher levels of blocking antibodies than the native sequence and 30-fold higher levels of pseudoviral neutralizing antibodies. An additional RBD protein has been engineered to eliminate the need for glycosylation, facilitating production and single-component nanoparticle display of the antigen. The engineered receptor binding domain (RBD) and spike protein antigens produce significant improvements in pre-clinical animal models and may be used to develop improved coronavirus vaccines.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Novel SARS-CoV-2 vaccine.
- Improved SARS-CoV-2 diagnostics using stabilized antigens.
- Method of designing vaccine candidates or stabilized antigens by computational optimization of amino acid identity, followed by additional sequence comparison and selection (Stabilizer for Protein Expression and Epitope Design (SPEEDesign)).

Competitive Advantages:

- Novel SARS-CoV-2 spike vaccine with improved breadth and duration of protection.
- Novel RBD monomer and nanoparticle designs that are more immunogenic and stable than the naturally occurring RBD sequence.
- Computational method of designing vaccine antigens.

Development Stage:

- Pre-clinical testing of the novel immunogens in non-human primates.

Inventors: Dr. Niraj Tolia and Dr. Thayne Dickey, both of NIAID.

Publications: “Design of the SARS-CoV-2 RBD vaccine antigen improves neutralizing antibody response”, <https://doi.org/10.1101/2021.05.09.443238>

Intellectual Property: HHS Reference No. E-045-2021-0-US-01 - U.S. Provisional Application No. 63/200,194, filed February 18, 2021; PCT/US2022/070744, filed February 1, 2022

Licensing Contact: To license this technology, please contact Peter Tung at 240-669-5483 or peter.tung@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the invention. For collaboration opportunities, please contact Peter Tung at 240-669-5483; peter.tung@nih.gov.

Dated: March 17, 2022.

Surekha Vathyam,

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Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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